

## **REMARKS**

Claims 11 and 13 have been canceled without prejudice or disclaimer. Applicants reserve the right to pursue the canceled subject matter in one or more continuing applications. Claims 24-98 are pending.

### **I. Summary of the Interview**

The undersigned contacted Examiner Sheinberg by telephone during the week of July 7, 2003 to discuss the instant restriction requirement. As the Examiner indicated that the case was being transferred to a different art unit, the substance of Applicants' position (described in detail below) was not discussed. In the event that the Examiner to whom this case is reassigned intends to maintain the instant election of species requirement, Applicants respectfully request an interview at the Examiner's earliest convenience.

### **II. The Election of Species Requirement**

Pursuant to Paper No. 0603, mailed June 17, 2003, the Examiner has required an election of "a single disclosed species to which the claims will be restricted if no generic claim is finally held to be allowable" under 35 U.S.C. § 121 (and presumably 37 C.F.R. § 1.146). In particular, the Examiner contends that:

This application contains claims directed to patentably distinct species of the claimed invention in that various epitopes, for example, the epitopes indicated on page 36 (lines 7-9) specific to SEQ ID NO:68. Applicants are to elect an antibody directed to an epitope due to different antibodies having different epitope markers.

The Examiner has noted that claims 24, 40, 47, 49, 61, 77, and 84 are generic.

While Applicants strongly disagree with the instant requirement, in order to be fully responsive, Applicants hereby elect, with traverse, the subject matter of an isolated antibody or fragment thereof that specifically binds to a protein consisting of amino acid residues 93 to 107 of SEQ ID NO:68, and to the equivalent residues encoded by the HPMBQ91 cDNA contained in ATCC Deposit No. 97922. Claims 24-98 are generic, and read on the provisionally elected species. Applicants reserve the right to file one or more divisional applications directed to non-elected species should the election of species requirement be made final as a result of no generic claim being held allowable.

Additionally, Applicants retain the right to petition from either the prior restriction requirement or the instant election of species requirement under 37 C.F.R. § 1.144.

With respect to the election of species requirement made by the Examiner, Applicants respectfully disagree and traverse. As a threshold matter, Applicants point out that as the “species” have been drawn by the Examiner, all of the pending claims are generic. No claim is directed to an antibody that specifically binds a particular epitope.<sup>1</sup>

For an election of species requirement to be proper under 37 C.F.R. § 1.146, “a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby,” must be pending in the application. Indeed, M.P.E.P. § 809.02(d) indicates that

Where only generic claims are presented, no restriction can be required except in those applications where the generic claims recite such a multiplicity of species that an unduly extensive and burdensome search is necessary. See MPEP § 808.01(a).

Although M.P.E.P. § 808.01(a) does indicate that an election of species requirement may be made in applications “in which no species claims are present and a generic claim recites such a multiplicity of species that an unduly extensive and burdensome search is required,” Applicants point out that both sections 808.01(a) and 809.02(d) require that the generic claim recite such a multiplicity of species, not simply read on them.

Applicants note that it is the claims that must be analyzed to determine whether an election of species requirement should be made. As M.P.E.P. § 814 and *Ex parte Ljungstrum* make clear, in making the election of species requirement, the Examiner should refer to “the particular limitations in the claims and the reasons why such limitations are considered to restrict the claims to a particular disclosed species.” Thus, the focus must be on the claimed invention, not on species that are disclosed in the specification but not the subject of a claim limitation.

As noted above, there are no species claims pending in the application, nor do the generic claims recite any species, much less an undue multiplicity of species.

Accordingly, pursuant to 37 C.F.R. § 1.146 and M.P.E.P. § 808.01(a), the instant election of species requirement is improper and should be reconsidered and withdrawn.

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<sup>1</sup> Indeed, Applicants question whether even claims to antibodies that specifically bind a particular epitope would be proper “species” claims under M.P.E.P. § 806.04(e), as such claims would not be restricted to a single disclosed embodiment. For example, multiple antibody types (IgG, IgA, IgM) would fall within the scope of such a claim, and antibodies with different polypeptide sequences that all specifically bind a particular epitope can easily be generated.

Accordingly, pursuant to 37 C.F.R. § 1.146 and M.P.E.P. § 808.01(a), the instant election of species requirement is improper and should be reconsidered and withdrawn.

Moreover, even where patentably distinct inventions appear in a single application, restriction (including election of species) is improper unless the examiner can show that the search and examination of these groups would entail a “serious burden.” *See* M.P.E.P. § 803. In the present situation, although the Examiner contends that the claims are directed to patentably distinct species, Applicants respectfully assert that the search of the instant claims will include all antibodies to the protein of the invention. In particular, many, if not most, publications disclosing antibodies to a protein do not disclose the particular epitope(s) to which those antibodies specifically bind. As such, the search will require a text search using the term “antibody” and the known names for the protein of the invention, as well as a sequence-based search on the protein of the invention. Since such a search will encompass all of the species envisioned by the Examiner, it cannot be a serious burden to search and examine all of the species embraced by generic claims 24-98. Nor would such a search be “unduly extensive and burdensome” as contemplated by M.P.E.P. §§ 808.01(a) and 809.02(d). Accordingly, the instant election of species requirement should be reconsidered and withdrawn.

Finally, Applicants respectfully assert that the instant requirement is also at odds with the established practice of Group 1600 with respect to generic claims directed to antibodies that bind a particular protein. There are many applications issued with generic antibody claims with no election of species requirement being made. Indeed, the undersigned has numerous applications with generic antibody claims pending and issued without such a requirement. Accordingly, if the Examiner intends to maintain the instant election of species requirement after consideration of the above, Applicants respectfully request a personal interview with the Examiner and Practice Specialist Paula Hutzell at the Examiner’s earliest convenience to discuss whether the instant requirement is consistent with the policy of Group 1600.

Applicants retain the right to petition from the election of species requirement under 37 C.F.R. § 1.144.

### **III. Correction of Inventorship**

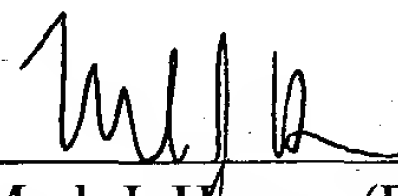
It has come to the attention of Applicants that Gregg A. Hastings has been erroneously omitted as an inventor of this application without deceptive intent. Applicants are currently obtaining the papers required to add Dr. Hastings as an inventor, and will file them as soon as possible.

### **CONCLUSION**

Entry of the above amendment and remarks is respectfully solicited. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application, or to schedule an interview as noted above. If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If an extension of time under 37 CFR § 1.136 is required, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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